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10/561,933

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Galit Levin

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WINSTON & STRAWN LLP  
PATENT DEPARTMENT  
1700 K STREET, N.W.  
WASHINGTON, DC 20006

EXAMINER

DOUKAS, MARIA E

ART UNIT

PAPER NUMBER

3767

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,933	<b>Applicant(s)</b> LEVIN ET AL.	
	<b>Examiner</b> MARIA E. DOUKAS	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-7, 9-10, 12-17, 19-20, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0010414 to Coston (Coston) in view of U.S. Patent No. 6,302,874 to Zhang (Zhang).

#### In Reference to Claims 1 and 3

Coston teaches a system (Figure 6) for intradermal or transdermal delivery of a molecule, such as an active agent (p. 2, paragraphs [0013-0014]) comprising: an apparatus for facilitating intradermal or transdermal delivery through the skin of a subject, the apparatus comprises a plurality of electrodes (Figure 6, electrode array 96); and a main unit (handle 70) comprising a control unit (p. 9, paragraph [0088]) which is adapted to apply electrical energy between two or more electrodes when the electrodes are in vicinity of the skin, typically generating current flow or one or more sparks, enabling ablation of stratum corneum in an area beneath the electrodes, thereby generating at least one micro-channel (p. 2, paragraphs [0013-0015]; p. 4, paragraphs [0045-0047], whereby the pore size created by the device ablating the stratum corneum falls within the description given by applicant of a microchannel). Coston also teaches

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whereby the active agent is applied to the skin after the microchannel is generated (p. 8, paragraph [0076]; p. 9, paragraphs [0088-0089]. Coston fails to teach wherein the active agent delivered is a cosmetic or dermatological composition and also fails to teach the plurality of electrodes being within an electrode cartridge.

Zhang teaches a handheld pulser (Figure 5A) for applying electric pulses to the skin in order to produce transient pores to facilitate transdermal delivery of a cosmetic agent composition (col. 7, lines 6-13) comprising at least one water-soluble, poorly water-soluble, or water-insoluble cosmetic agent and an acceptable carrier (col. 6, lines 42-53) that is devoid of permeation enhancers (col. 8, lines 33-54, whereby the permeation enhancer is described as being an optional treatment method and, therefore, the composition is capable of being devoid of the permeation enhancers) in order to improve the appearance of the skin (col. 1, lines 13-17). Zhang further teaches the handheld pulser having an electrode cartridge with a plurality of electrodes (col. 12, lines 30-31, lines 52-53; electrode 2 in Figure 5A; col. 14, lines 24-62) in order to enable the electrode to be detachable to allow different electrode types and/or shapes to be used (col. 14, lines 24-29).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Coston to have an electrode cartridge to contain the plurality of electrodes as taught by Zhang in order to enable the electrode to be detachable to allow different electrode types and/or shapes to be used (col. 14, lines 24-29). Zhang teaches that the detachable electrode cartridge can be mounted to support means of the handheld pulser using clips or a mounting bracket as

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examples of attachment means (col. 14, lines 24-39), and that one example shape is a tube (Figure 6E) that would allow the electrode to be rolled along the skin (col. 14, lines 49-54). The device taught by Coston has a roller body 90 that contains the electrode array 96 and is attached via arms 80 to the handle 70, so it would be possible to modify the device of Coston to have a detachable electrode cartridge containing the plurality of electrodes that is attached to the arms 80 and still maintains the capability of being rolled along the skin to create microchannels. In addition, as Coston teaches the device is used to transport active agents, but does not limit it to those described (p. 6, paragraph [00061]), it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Coston to deliver a cosmetic agent composition devoid of permeation enhancers as taught by Zhang in order to improve the appearance of the skin (col. 1, lines 13-17).

#### In Reference to Claim 4

Coston in view of Zhang teaches the system of claim 1 (see rejection of claim 1 above). Coston further teaches wherein the electrical energy is of radio frequency (p. 2, paragraph [0016], whereby the frequency of 30 Hz-10,000 kHz falls within the radio frequency range defined by wikipedia.com to be "any frequency within the electromagnetic spectrum associated with radio wave propagation").

#### In Reference to Claim 5

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Coston in view of Zhang teaches the system of claim 1 (see rejection of claim 1 above). Zhang further teaches wherein the cosmetic agent is selected from the group consisting of xanthines, retinoids,  $\alpha$ -hydroxy acids,  $\beta$ -hydroxy acids,  $\alpha$ -2 adrenergic inhibitors,  $\beta$ -adrenergic agonists, aromatase inhibitors, anti-estrogens, hydroquinone, ascorbic acid, kojic acid, corticosteroids, mucopolysaccharides, collagen, estrogens, isoflavonoids, cinnamic acid, benzoyl peroxide, tropolone, catechol, mercaptoamine, niacinamide, tocopherol, ferulic acid, azelaic acid, botulinum, urea, a derivative or salt thereof (col. 7, lines 45-48).

#### In Reference to Claim 6

Coston in view of Zhang teaches the system of claim 5 (see rejection of claim 5 above). Since claim 5 lists a Markoush grouping, claim 6 further specifies xanthine from the group as caffeine, however ascorbic acid can still be chosen as the cosmetic agent from the claim 5 group, thus meeting claim 6).

#### In Reference to Claim 7

Coston in view of Zhang teaches the system of claim 5 (see rejection of claim 5 above). Since claim 5 lists a Markoush grouping, claim 7 further specifies  $\beta$ -hydroxy acid from the group as salicylic acid, however ascorbic acid can still be chosen as the cosmetic agent from the claim 5 group, thus meeting claim 7).

#### In Reference to Claim 9

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Coston in view of Zhang teaches the system of claim 1 (see rejection of claim 1 above). Zhang further teaches wherein the cosmetic or dermatological composition further comprising at least one component selected from the group consisting of surfactants, humectants, preservatives, antioxidants, powders, clarifying agents, coloring agents, opacifiers, thickeners, and perfumes (col. 1, line 40).

#### In Reference to Claim 10

Coston in view of Zhang teaches the system of claim 1 (see rejection of claim 1 above). Coston further teaches that the drug applied to the pretreated site can be a pharmaceutical agent (p. 8, paragraph [0076]).

#### In Reference to Claim 12

Coston in view of Zhang teaches the system of claim 1 (see rejection of claim 1 above). Zhang further teaches wherein the cosmetic or dermatological composition is formulated in a form selected from the group consisting of anhydrous compositions, aqueous solutions, aqueous suspensions, oil-in-water emulsions, water- in-oil emulsions, oily droplets in aqueous solutions, micelles, liposomes, ethosomes, and aqueous suspensions of nanoparticles (col. 6, lines 53-57).

#### In Reference to Claim 13

Coston in view of Zhang teaches the system of claim 1 (see rejection of claim 1 above). Zhang further teaches wherein the cosmetic or dermatological composition is in

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a form selected from the group consisting of lotions, creams, ointments, gels, pastes, sprays, foams, sticks, and skin patches (col. 6, lines 53-57).

#### In Reference to Claims 14 and 24

Coston teaches a method comprising generating at least one micro-channel in an area of skin of a subject and then topically applying a drug to the area of skin where the micro-channels are present (p. 8, paragraph [0076]). Coston in view of Zhang as described in the rejection of claim 1 above describes the apparatus used to generate the micro-channel and describes the use of a cosmetic composition. Therefore, the apparatus as described in rejection of claim 1 above, when used in conjunction with the cosmetic composition of Zhang (also see claim 1 rejection) would provide a method for treating a skin condition, as Zhang teaches the cosmetic composition can be used for treatment of skin conditions (col. 5, lines 46-67).

#### In Reference to Claim 15

Coston in view of Zhang teaches the system of claim 14 (see rejection of claim 14 above). Zhang further teaches wherein the cosmetic agent is selected from the group consisting of xanthines, retinoids,  $\alpha$ -hydroxy acids,  $\beta$ -hydroxy acids,  $\alpha$ -2 adrenergic inhibitors,  $\beta$ -adrenergic agonists, aromatase inhibitors, anti-estrogens, hydroquinone, ascorbic acid, kojic acid, corticosteroids, mucopolysaccharides, collagen, estrogens, isoflavonoids, cinnamic acid, benzoyl peroxide, tropolone, catechol,



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mercaptoamine, niacinamide, tocopherol, ferulic acid, azelaic acid, botulinum, urea, a derivative or salt thereof (col. 7, lines 45-48).

In Reference to Claim 16

Coston in view of Zhang teaches the system of claim 15 (see rejection of claim 15 above). Since claim 15 lists a Markoush grouping, claim 16 further specifies xanthine from the group as caffeine, however ascorbic acid can still be chosen as the cosmetic agent from the claim 15 group, thus meeting claim 16).

In Reference to Claim 17

Coston in view of Zhang teaches the system of claim 15 (see rejection of claim 15 above). Since claim 15 lists a Markoush grouping, claim 17 further specifies  $\beta$ -hydroxy acid from the group as salicylic acid, however ascorbic acid can still be chosen as the cosmetic agent from the claim 15 group, thus meeting claim 17).

In Reference to Claim 19

Coston in view of Zhang teaches the system of claim 14 (see rejection of claim 14 above). Zhang further teaches wherein the cosmetic or dermatological composition further comprising at least one component selected from the group consisting of surfactants, humectants, preservatives, antioxidants, powders, clarifying agents, coloring agents, opacifiers, thickeners, and perfumes (col. 1, line 40).

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In Reference to Claim 20

Coston in view of Zhang teaches the system of claim 14 (see rejection of claim 14 above). Coston further teaches that the drug applied to the pretreated site can be a pharmaceutical agent (p. 8, paragraph [0076]).

In Reference to Claim 22

Coston in view of Zhang teaches the system of claim 14 (see rejection of claim 14 above). Zhang further teaches wherein the cosmetic or dermatological composition is formulated in a form selected from the group consisting of anhydrous compositions, aqueous solutions, aqueous suspensions, oil-in-water emulsions, water- in-oil emulsions, oily droplets in aqueous solutions, micelles, liposomes, ethosomes, and aqueous suspensions of nanoparticles (col. 6, lines 53-57).

In Reference to Claim 23

Coston in view of Zhang teaches the system of claim 14 (see rejection of claim 14 above). Zhang further teaches wherein the cosmetic or dermatological composition is in a form selected from the group consisting of lotions, creams, ointments, gels, pastes, sprays, foams, sticks, and skin patches (col. 6, lines 53-57).

3. Claims 8, 11, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coston in view of Zhang as applied to claims 5, 10, 15, and 20 above, and further in view of U.S. Patent No. 6,477,410 to Henley (Henley).

In Reference to Claims 8 and 18

Coston in view of Zhang teaches the system of claims 5 and 15 (see rejection of claims 5 and 15 above) but fails to teach wherein the cosmetic agent is hydroquinone. Henley teaches delivery of cosmetic agents that can include hydroquinone (col. 4, lines 65-66) in order to remove pigmentation from hyperpigmented areas of skin (Merriam-Webster definition). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Coston in view of Zhang to deliver hydroquinone as the cosmetic agent as taught by Henley in order to remove pigmentation from hyperpigmented areas of skin (Merriam-Webster definition).

In Reference to Claims 11 and 21

Coston in view of Zhang teaches the system of claims 10 and 20 (see rejection of claims 10 and 20 above) but fails to teach wherein the pharmaceutical agent is an antibacterial agent. Henley teaches the delivery of a pharmaceutical agent that can be an antibacterial agent (col. 2, lines 9-11; col. 4, lines 49-50) in order to inhibit bacterial growth (Merriam-Webster definition). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Coston in view of Zhang to deliver an antibacterial agent as taught by Henley in order to inhibit bacterial growth (Merriam-Webster definition).

***Response to Arguments***

4. Applicant has submitted an expectable declaration on 9/3/2008 and therefore the objection is withdrawn.
5. Applicant submitted two new figures 9 and 10 on 8/28/2008 which are accepted by examiner.
6. Applicant's amendment to claim 24 has overcome the objection, and the objection is therefore withdrawn.
7. Applicant's arguments with respect to claims 1 and 3-24 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767